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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/057,150    04/07/98    CLARY

D    233/187

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EXAMINER
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EASLIN	
ART UNIT	PAPER NUMBER

1646

DATE MAILED:

11/21/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/057,150

Applicant(s)  
CLARY, DOUGLAS

Examiner  
Nirmal. S. Basi

Group Art Unit  
1646



☒ Responsive to communication(s) filed on Aug 29, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1, 6-8, 11, 16-18, and 20-29 is/are pending in the application.

Of the above, claim(s) 1, 6-8, 11, 16-18, and 20-22 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1, 6-8, 11, 16-18, and 20-29 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1646

### DETAILED ACTION

1. Amendment filed 8/29/00 has been entered.

#### *Election/Restriction*

2. Applicant's Election of Species, with traverse, of the non-peptide organic molecule in claim 23, cell survival in claim 24, phosphatase in claim 28, and phenotype is protein kinase catalytic activity in claim 23, in Paper No. 15 (8/29/00), is acknowledged. The traversal is on the ground(s) that the Election of Species "is improper (see MPEP 806 et. seq.)" This is not found persuasive because applicant has not specifically disclosed why the Election of Species "is improper".

The requirement is still deemed proper and is therefore made FINAL.

#### *Claim Rejections - 35 USC § 101 and 35 USC § 112, 1st paragraph*

The following is a quotation of 35 U.S.C. 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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3. Claims 23-29 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

A "specific utility" is a utility that is specific to the subject matter claimed, as opposed to a  
5 "general utility" that would be applicable to the broad class of the invention. A "substantial utility" is a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. A "well established utility" is a utility that is well known, immediately apparent, or  
10 implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. A "well established utility" must also be specific and substantial as well as credible.

Based on the record, there is not a "well established utility" for the claimed invention.

Applicant has asserted utilities for the specifically claimed invention of claims 23-29.

The claims are directed to method of identifying one or more compounds that modulate  
15 the function of C-RET receptor protein kinase.

The specification discloses the C-RET is an "orphan receptor". The specification further describes, "It is called a an orphan receptor because no ligand has been identified which directly activates it. In addition, the term "orphan receptor" as used herein refers to an RPTK without a known function. Alternatively, an orphan RPTK may be activated by a ligand known in the art,  
20 but the ligand has not been shown to directly activate the receptor of interest in the art", see page

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16, lines 6-26. The specification discloses, "The invention described herein relates generally to methods of determining receptor tyrosine kinase function in cells or tissues. The methods activate a receptor in a ligand independent manner", page 1, lines 16-20.

5 The specification discloses C-RET is an orphan receptor, which by applicants own admission, is a receptor without a function and the specification does not disclose any disease states disclosed that are directly related to C-RET dysfunction.

10 The utilities asserted by Applicant are not specific or substantial. Thus the corresponding asserted utilities are essentially methods of using C-RET to identify the function of C-RET and as targets for drug discovery. Testing for compounds that interact with "orphan receptors" which may be implicated in an unspecified, undisclosed disease or condition would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use. Since neither the specification nor the art of record disclose any activities or properties that would constitute a "real world" context of use for the claimed C-RET, further experimentation is necessary to attribute a utility to C-RET. See Brenner v. Manson, 383 U.S. 519, 535-36, 148  
15 USPQ 689, 696 (1966) (noting that "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing", and stated, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.").

4. Claims 23-29 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since  
20 the claimed invention is not supported by either a specific and substantial asserted utility or a well

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established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Since C-RET is described as an "orphan receptor" neither the specification nor the art of record disclose any activities or properties that would constitute a "real world" context of use for C-RET, further experimentation is necessary to attribute a utility to the compounds identified the methods of instant application. The specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected use the compounds identified by the method of claims 23-29 without undue experimentation.

No claim is allowed.

#### Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi  
Art Unit 1646  
November 19, 2000

  
YVONNE EYLER, PH.D  
PRIMARY EXAMINER